First attempt success ratio of intravenous cannulation with the Veinplicity®

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24775

Source
Nationaal Trial Register

Brief title
VEINPLICITY STUDY

Health condition

Difficult intravenous access, unsuccessful attempt to insert a peripheral intravenous catheter.

Sponsors and support

Primary sponsor: Catharina Hospital
Department of anesthesiology, intensive care and pain medicine
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Source(s) of monetary or material Support: Physeon GmbH.
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Intervention

Outcome measures

Primary outcome

The primary outcome is the first attempt success ratio of peripheral intravenous catheter placement with the use of the Veinplicity® device, when compared to the traditional landmark technique, in patients with a medium-risk profile according to the A-DIVA scale. The outcome of interest is to reach a success ratio of 95% upon inserting a peripheral intravenous catheter by using the Veinplicity® device, in patients with a medium-risk profile according to the A-DIVA scale.

Secondary outcome

As secondary objectives, we are interested in the effects on:

The time needed for intravenous cannulation;

Patients satisfaction;

Pain score upon intravenous cannulation;

Practitioners satisfaction;

The relation between the success ratio and patients demographics (age, sex, length, weight, skin color, dominant side, A-DIVA score, medical history and comorbidities);

The relation between the success ratio and procedure related data (size of the vein, size of the inserted catheter, side of cannulation, site of cannulation).

Study description

Background summary

The Veinplicity® device (Physeon, Schaffhausen, Switzerland) is an electrical stimulation device, which can be used as an adjunct for peripheral intravenous cannulation. It is said to increase local intravascular blood volume and therefor improves a practitioners' ability to gain intravenous access. Because of this statement, we hypothesize that the first attempt success ratio of peripheral intravenous cannulation will be increased in patients with a medium-risk profile according to the A-DIVA scale, with the use of the Veinplicity® device, when compared to the traditional landmark technique

Study objective

We hypothesize that the first attempt success ratio of peripheral intravenous cannulation will be increased in patients with a medium-risk profile according to the A-DIVA scale, with the use of the Veinplicity® device, when compared to the traditional landmark technique. In addition, the aim of the current study is to prove whether or not the Veinplicity® increases the first attempt success ratio of peripheral intravenous cannulation in patients with a medium-risk profile according to the A-DIVA scale, and hereby has an added value in reducing the incidence of a difficult intravenous access.

Study design

The study will be performed upon the procedure of inserting a intravenous catheter, on which the registrations will be done. A peripheral intravenous catheter is a small hollow catheter that is advanced over a needle into a peripheral vein through the skin. A peripheral intravenous catheter will be inserted in the upper extremity, and veins on the dorsal and ventral surfaces of the upper extremity are considered for peripheral cannulation, including the metacarpal, cephalic, basilic, and median veins. Intravenous cannulation was performed according to practice guidelines.

Intervention

In patients in the intervention group, a peripheral intravenous catheter will be inserted with the aid of the Veinplicity® device. For the control group, a historical cohort will be used. The Veinplicity® device is an electrical stimulation device, which can be used as an adjunct for peripheral intravenous cannulation. It increases local intravascular blood volume and therefor improves a practitioners' ability to gain intravenous access. The device utilizes a current to induce a physiological response that increases the blood flow in the peripheral vessel. It thickens the vein wall, increases stability, and expands the diameter of the vein, leading to easier vascular access. The two disposable electrodes are applied to the patient on the bicep and palm of the hand, and connected to the main cable to enable stimulation. Patients should be stimulated between 2 and 10 minutes, depending on the individual profile of the patient and condition of the veins. The device automatically switches off after 15 minutes of stimulation. Engorged veins remain palpable for 10 to 30 minutes after stimulation. After simulation, peripheral intravenous cannulation will be performed according to practice guidelines.

Contacts

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Eligibility criteria

Inclusion criteria

In order to be eligible to participate in this study, a patient must meet all of the following criteria:

Patients must be in the age of 18 years or older;

Patients with a medium risk profile on the A-DIVA scale (score 2 or 3);

Patients must be conscious and be able to adequately answer questions.

Exclusion criteria

A potential patient who meets any of the following criteria will be excluded from participation in this study:

Patients in which an intravenous catheter is already inserted on the ward;

Patients with medical devices in the body (pacemaker, ICD, trans-cerebral electrode placement, electrode placement that applies current to the carotid sinus region, other neurostimulators);

Patients who do not understand questions or generate adequate data, due to physical or communicational disorders.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2017
Enrollment:	125
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44449
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL6283
NTR-old	NTR6457
CCMO	NL61818.100.17
OMON	NL-OMON44449

Study results

Summary results
N/A